

In re Application of:
Lee and McPherron
Application No.: 09/628,112
Filed: July 27, 2000
Page 8

PATENT
Attorney Docket No.: JHU1120-11

II. REMARKS

Upon entry of the amendment, claims 1 to 3 and 34 to 45 will be pending. A marked version showing the amendments to the Title and the claims is attached hereto as Exhibit A.

Applicants and Applicants' representatives gratefully acknowledge the careful consideration of the application and helpful suggestions made by the Examiner and the Examiner's supervisor in the telephone interview held on August 29, 2002.

A. Regarding the Amendments

The Title has been amended to correspond more closely to the subject matter under prosecution. As such, the amendment merely addresses a formality, and does not add new matter.

Claims 4 to 18 and, pursuant to the restriction requirement, claims 19 to 33 have been cancelled herein without disclaimer, and without prejudice to Applicants' pursuing prosecution of subject matter encompassed within one or more of the claims in an application claiming the benefit of priority of the subject application.

Claim 1 has been amended to more clearly refer to "peptides comprising a promyostatin signal peptide domain corresponding to amino acid residues about 1 to 20 of a full length promyostatin". The amendment is supported, for example, by Figure 1, which exemplifies ten full length promyostatin sequences, and, for example, at page 16, line 17, to page 17, line 20; and page 21, lines 12-17. As such, it is submitted that the amendment does not add new matter.

Claim 3 has been amended to incorporate the language of previously pending claims 4, 5, and 6, which have been cancelled herein. As such, the amendment does not add new matter.

In re Application of:
Lee and McPherron
Application No.: 09/628,112
Filed: July 27, 2000
Page 9

PATENT
Attorney Docket No.: JHU1120-11

New claims 34 to 45 have been added. The new claims are supported by the specification and based on originally filed claims 1 to 3, which have been amended herein, and originally filed claims 4 to 18, which have been cancelled herein. More specifically, new claims 34 to 39 are supported by originally filed claims 1, 3 to 6, 8, 11, 12, 14 and 15; and new claims 40 to 43 are supported by originally filed claims 1, 3 to 6, 8, 16 and 17. In addition, new claims 34 to 43 are supported, for example, by Figure 1, which exemplifies ten full length promyostatin sequences, and at page 16, line 17, to page 17, line 20; and page 21, lines 12-17, of the specification. New claims 44 and 45 are based on originally filed claims 1, 8 and 13, and on originally filed claims 1, 8 and 18, respectively. As such, it is submitted that the newly added claims do not add new matter.

For the reasons set forth above, it is submitted that the amendments do not add new matter. Furthermore, the amendments do not require a new search or consideration, except with respect to the additional species (see Section B, below), because the claims as amended encompass the subject matter that has been of issue in this case. It is further submitted that the amendments place the claims in condition for allowance, or in better condition for appeal. In addition, more claims were cancelled than were added and, therefore, the amendment does not result in a greater number of claims pending than were pending prior to the final Office Action. As such, entry of the amendments is respectfully requested.

B. Regarding the Species Election

It was stated in the Office Communication mailed July 12, 2001 (Paper No. 10), that, upon allowance of a generic claim, additional species (in addition to elected murine GFD-8; SEQ ID NO:4) would be considered if written in dependent form. For the reasons discussed below, it is submitted that generic claims 1, 34 and 40 are allowable. Claims directed to the additional species have been written as dependent from claims 1, 34 and 40. Accordingly, consideration of the additional species is respectfully requested.

In re Application of:
Lee and McPherron
Application No.: 09/628,112
Filed: July 27, 2000
Page 10

PATENT
Attorney Docket No.: JHU1120-11

C. Double Patenting Rejection

The rejection of claims 1 to 3 under the judicially established doctrine of obviousness-type double patenting over claim 1 of U.S. Pat. No. 5,827,733 is respectfully traversed.

Applicants have submitted herewith a Terminal Disclaimer, disclaiming the term of any patent that issues from the subject application that may extend beyond the term of U.S. Pat. No. 5,827,733. Accordingly, it is respectfully requested that this rejection be removed.

D. Rejections under 35 U.S.C. § 112

The objection to the specification and corresponding rejection of claims 1 to 3, 8 to 12 and 14 to 17 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description are respectfully traversed. It is noted that claims 8 to 12 and 14 to 17 have been cancelled. As such, the rejection is addressed with respect to the claims as amended and to the newly added claims.

It is stated in the Office Action that the specification discloses that the C-terminal region of myostatin can interact with its receptor and affect signal transduction, and that the prodomain of promyostatin can interact with the mature or parent protein. It is alleged, however, that the disclosure of these two regions is not sufficient to define the claimed genus, which encompasses subgenera of molecules having diverse functions and, therefore, diverse functional requirements (Office Action, page 4). It is stated, for example, that no structural characteristics or sequences required for any particular function have been set forth, and that there is no description of features that would be required for activators, inhibitors or other molecules.

The claims have been amended, or new claims have been added, to more clearly indicate the structural features and functional activities of the claimed peptides of a full length promyostatin polypeptide, and, as set forth in the response to the previous Office Action, the specification provides examples of such peptides having the required structures and functions. Accordingly, it is submitted that the skilled artisan would have known that Applicants were in possession of the claimed promyostatin peptides having the recited structural and functional features and, therefore, respectfully

In re Application of:
Lee and McPherron
Application No.: 09/628,112
Filed: July 27, 2000
Page 11

PATENT
Attorney Docket No.: JHU1120-11

requested that the rejection of the claims as lacking an adequate written description in the specification be removed.

The objection to the specification and corresponding rejection of claims 1 to 3, 8 to 12 and 14 to 17 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement are respectfully traversed.

It is acknowledged in the Office Action that the specification enables mature myostatin proteins and the promyostatin proregion. It is alleged, however, that the specification does not enable all functional peptide portions of a promyostatin polypeptide encompassed within the claims. As discussed above, the claims have been amended, and new claims have been added, to more clearly recite structural features of the claimed promyostatin peptides and the functional activities associated the specific peptides. Accordingly, it is respectfully requested that the rejection of the claims as allegedly lacking enablement by the specification be removed.

The rejection of claims 1 to 3, 8 to 12 and 14 to 17 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter of the invention is respectfully traversed.

It is alleged in the Office Action that the terms "functional peptide portions" and "proteolytic fragments" are indefinite because the specification does not define the limits of such portions or fragments and because there is no definition of "functional." As such, it is alleged that one skilled in the art would not know what molecules meet the limitations of the claims.

The term "proteolytic fragment" has been deleted from the claims and the "functional" activities of the claimed peptide portions of promyostatin have been recited in the claims. As such, it is submitted that the skilled artisan, reading the claims in view of the specification, would know the subject matter encompassed within the claims and, therefore, is respectfully requested that this rejection of the claims under 35 U.S.C. § 112, second paragraph, be removed.

In re Application of:
Lee and McPherron
Application No.: 09/628,112
Filed: July 27, 2000
Page 12

PATENT
Attorney Docket No.: JHU1120-11

In view of the amendments and new claims, and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

No additional fee other than that submitted herewith is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, the Commissioner is authorized to charge any fee (or credit any overpayment) to Deposit Acct. No. 50-1355.

Respectfully submitted,

Dated: September 12, 2002

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Encls. Exhibit A

In re Application of:
Lee and McPherron
Application No.: 09/628,112
Filed: July 27, 2000
Exhibit A - Page 1

PATENT
Attorney Docket No.: JHU1120-11

EXHIBIT A
MARKED VERSION SHOWING THE AMENDMENTS
TO THE TITLE AND THE CLAIMS

The Title has been amended as follows:

PROMYOSTATIN PEPTIDES[AND METHODS OF USING SAME]

Claims 1 and 3 have been amended as follows:

1. (Amended) A substantially purified peptide [portion] of a promyostatin polypeptide, said peptide comprising a promyostatin signal peptide domain corresponding to amino acid residues about 1 to 20 of a full length promyostatin polypeptide, said peptide having signal peptide activity.

3. (Amended) The peptide of claim 1, wherein the promyostatin polypeptide [is selected from the group consisting of:] comprises:

a human promyostatin polypeptide having an amino acid sequence as set forth in SEQ ID NO: 2; [and]

a murine promyostatin polypeptide having an amino acid sequence as set forth in SEQ ID NO: 4;

a rat promyostatin polypeptide having an amino acid sequence as set forth in SEQ ID NO: 6;

a chicken promyostatin polypeptide having an amino acid sequence as set forth in SEQ ID NO: 8;

a baboon promyostatin polypeptide having an amino acid sequence as set forth in SEQ ID NO: 10;

a bovine promyostatin polypeptide having an amino acid sequence as set forth in SEQ ID NO: 12;

In re Application of:

Lee and McPherron

Application No.: 09/628,112

Filed: July 27, 2000

Exhibit A - Page 2

PATENT

Attorney Docket No.: JHU1120-11

a porcine promyostatin polypeptide having an amino acid sequence as set forth in SEQ

ID NO: 14;

an ovine promyostatin polypeptide having an amino acid sequence as set forth in SEQ ID

NO: 16;

a turkey promyostatin polypeptide having an amino acid sequence as set forth in SEQ ID

NO: 18; or

a zebrafish promyostatin polypeptide having an amino acid sequence as set forth in SEQ

ID NO: 20.